

DETAILED ACTION

Claims 1, 2 and 4-15 are currently pending in the instant application. Applicants have cancelled claim 3 and added new claims 9-15 in an amendment filed on March 10, 2008. The Examiner wants to point out that even though claims 5-8 are withdrawn, the actual claims need to be present.

I. *Response to Arguments*

Applicants' amendment, March 10, 2008, has overcome the rejection of claim 4 under 35 USC 112, second paragraph as being indefinite; the rejection of claims 2-4 under 35 USC 112, first paragraph as failing to comply with the enablement requirement and the objection of claims 1-4 as being dependent upon a rejected base claims. The rejections and objection have been withdrawn.

However, the amendment did not overcome the rejection of claim 1 under 35 USC 112, first paragraph for scope of enablement. This rejection is maintained and the new claims 9-15 are rejected as well. The rejection will be discussed in further detail below.

II. *Information Disclosure Statement*

The information disclosure statement (IDS) submitted on January 12, 2006 is not in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has not been considered by the examiner. The Examiner initialed the 1449 previously in error but the IDS has not been considered because Applicants have failed to submit the Farina, et al. reference.

III. **Rejection(s)**

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 9-15 are rejected under 35 U.S.C. 112, first paragraph, while the specification provides enablement for a method of **treating** urinary incontinence, overactive bladder or pollakiuria but does not provide enablement for a method of inhibiting urinary incontinence, overactive bladder or pollakiuria or a method of treating or inhibiting diseases associated with detrusor instability, cystitis, urethritis and kidney stone ailments. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,

5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The nature of the invention

Applicants are claiming a method of treating urinary incontinence, overactive bladder and pollakiuria. Support for the intended use is found on pages 16-17 which is data for patch clamp studies of BK current in freshly isolated bladder smooth muscle cells and the effects of compounds on KCl-induced contraction of isolated urinary bladder strips.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that the pharmaceutical art, for example, remain highly unpredictable. Enablement for the scope of treating or inhibiting diseases associated with detrusor instability, cystitis, urethritis and kidney stone ailments is not present in the specification.

Applicants' claims are therefore drawn to a method for treating or inhibiting cystitis. It is the state of the art that cystitis is also known as urinary tract infection which can happen anywhere along the urinary tract. Cystitis, a common condition, is usually caused by bacteria entering the urethra and then the bladder which leads to inflammation and infection in the lower urinary tract. A mild case of cystitis may go away

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on its own without treatment. Because of the risk of the infection spreading to the kidneys, however, antibiotics are usually recommended. A chronic or recurrent UTI should be treated thoroughly because of the chance of kidney infection. Antibiotics may need to be given for a long period of time, or stronger antibiotics may be needed than for single, uncomplicated episodes of cystitis.

(See UTL: <http://www.nlm.nih.gov/medlineplus/ency/article/000521.htm>)

Applicants' claims are therefore drawn to a method for treating or inhibiting urethritis. It is the state of the art that urethritis is inflammation of the urethra from any cause. Urethritis may be caused by bacteria or a virus. The same bacteria that cause urinary tract infections (*E. coli*) and some sexually transmitted diseases (Chlamydia, gonorrhea) can lead to urethritis. Viral causes of urethritis include herpes simplex virus and cytomegalovirus. The goal of therapy is to improve symptoms, prevent spread of infection and eliminate the cause of infection. Antibiotic therapy should target the specific organism causing the infection. Pain relievers (including pyridium, which works specifically on the urinary tract) may be used along with antibiotics. (See UTL: <http://www.nlm.nih.gov/medlineplus/ency/article/000439.htm>)

There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The amount of direction or guidance present and the presence or absence of working examples

There is no evidence of record, which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the numerous diseases or disorders claimed herein. That a single class of compounds can be used to treat or control all diseases embraced by the claims is an incredible finding for which Applicants have not provided supporting evidence. Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use for treating or inhibiting any or all conditions by administering the instant claimed compounds.

The breadth of the claims

The breadth of the claims is a method of treating urinary incontinence, overactive bladder, pollakiuria, diseases associated with detrusor instability, cystitis, urethritis and kidney stone ailments.

The quantity of experimentation needed

The nature of the pharmaceutical arts is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities for each of the diseases and disorders instantly claimed. The quantity of experimentation needed would be undue when faced with the lack of direction and guidance present in the instant specification in regards to testing all diseases and disorders generically embraced in the claim language, and when faced with the unpredictability of the

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pharmaceutical art. Thus, factors such as “sufficient working examples”, “the level of skill in the art” and predictability, etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims.

The level of the skill in the art

Even though the level of skill in the pharmaceutical art is very high, based on the unpredictable nature of the invention and state of the prior art and lack of guidance and direction, one skilled in the art could not use the claimed invention without undue experimentation.

The rejection can be overcome by, for example, amending the claims to read on the subject matter that the Examiner has indicated is enabled by the specification.

Claims 1 and 9-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The terms “diseases associated with detrusor instability” and “kidney stone ailments” are not defined in the specification so as to know the diseases or conditions that are included and/or excluded by the term. Therefore, the specification lacks adequate support for Claims 1 and 9-15.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 9-15 are rejected under 35 U.S.C. 112, second paragraph, as

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being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the diseases "overactive bladder", "urge incontinence" and "irritable bladder" are alternative names of each other and ultimately refer to the same disease. So it is unclear what Applicants are actually trying to claim in claim 1.

(see URL: <http://www.nlm.nih.gov/medlineplus/ency/article/001270.htm>)

IV. Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 7:00 AM-3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shawquia Young/

Examiner, Art Unit 1626

/Kamal A Saeed, Ph.D./

Primary Examiner, Art Unit 1626